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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,833	04/14/2004	Dennis A. Carson	023070-131710US	7743

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EXAMINER

MOORE, SUSANNA

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/824,833	Applicant(s) CARSON ET AL.	
	Examiner Susanna Moore	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-118 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to compounds of the formula in claim 1, wherein pyrrolo[2,3-d]pyrimidines or pyrrolo[3,2-d]pyrimidines are formed, and compositions thereof, classified in class 544, subclass 280 and 232; subclass 265.1.
- II. Claims 1-13, drawn to compounds of the formula in claim 1, wherein pyrido[2,3-d]pyrimidines are formed, and compositions thereof, classified in class 279 and 232, subclass 264.11.
- III. Claims 1-13, drawn to compounds of the formula in claim 1, wherein thiazolo[4,5-d]pyrimidines are formed, and compositions thereof, classified in class 255 and 232, subclass 260.1.
- IV. Claims 14-51, drawn to a nucleic acids in claim 14, compositions and method of treatments thereof, classified in class 536, subclass 23.1 and class 514, subclass 44.
- V. Claims 52-63, drawn to a method of treating a viral infection by administering a toll-like receptor ligand (TRL) and an inhibitor of inosine monophosphate dehydrogenase (IMPDH), classification will be based upon the disease elected.
- VI. Claims 64-82 and 112-113, drawn to a method of treating cancer by administering an inhibitor of inosine monophosphate dehydrogenase (IMPDH) and an interferon inducer, classification will be based upon the disease elected.

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- VII. Claims 83-100 and 116-117, drawn to a method of an autoimmune disease by administering an inhibitor of inosine monophosphate dehydrogenase (IMPDH) and an interferon inducer, classification will be based upon the disease elected.
- VIII. Claims 101-111, drawn to a method of treating a disease accessible to topical treatment, classification will be based upon the disease elected.
- IX. Claims 114-115, drawn to a method of treating a viral infection by administering mizoribine, mizoribine base or mizoribine aglycon in combination with a Type I interferon, classification will be based upon the disease elected.
- X. Claim 118, drawn to a method of treating Crohn's disease by administering an inhibitor of inosine monophosphate dehydrogenase (IMPDH) and a probiotic and/or a glycolipid, classification will be determined upon election of group.

Note: Election of Group IV requires election of a particular nucleotide in claim 14.

Election of one of the groups V-X requires election of a disease and a particular inhibitor.

Groups I-III are independent and distinct from each other as they are drawn to compounds of the formula in claim 1. Group (I) encompasses bicyclic compounds of the first structure of claim 1, wherein A= 5,6-dihydropyridin-2(1H)-one. Group (II) is drawn to bicyclic compounds, wherein A= thiazolidin-2-one. The bicyclic compounds of group (III) covers

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compounds represented by the two bottom structures in claim 1, wherein A= pyrrolo[3,2-b] and pyrrolo[2,3-b].

Each of groups I-III are directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of actions, different effects, and reactive conditions. It is noted that a reference disclosing a compound of one group would not necessarily disclose a compound of the other two groups. Additionally, the level of skill in the art is not such that one invention would be obvious over the other, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, while chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Thus, by virtue of the different structures presented in groups I-III, these inventions are distinct. Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963), and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Groups I-III and IV are independent and distinct from each other as Group I-III are drawn to compounds of the formula in claim 1 and Group IV is drawn to a nucleic acid of claim 14.

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The compounds of Groups I-III encompass heterobicyclic compounds, which may or may not have carbohydrates at the R4 position. Group IV is drawn to nucleic acids, which contain at least one of the modified nucleotides found in claim 14. The bicyclic compounds of Groups I-III differ from those of Group IV in that a nucleic acid maybe formed with the compounds in Group IV, while the compounds of Groups I-III are heterobicyclic compounds, not polymers. An election of a compound in claim 14 is required if Group IV is elected.

Inventions V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions V-X are drawn to method of treatments and are not dependent on any compound claims. Each of the groups V-X are drawn to method of treatments of different diseases and disorders. Since groups V-X are drawn to “umbrella terms,” i.e. autoimmune disease consists of hundreds of diseases, an election of a disease and an inhibitor is required for Groups V-X.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Beth L. Kelly on September 15, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made. A written restriction was requested.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

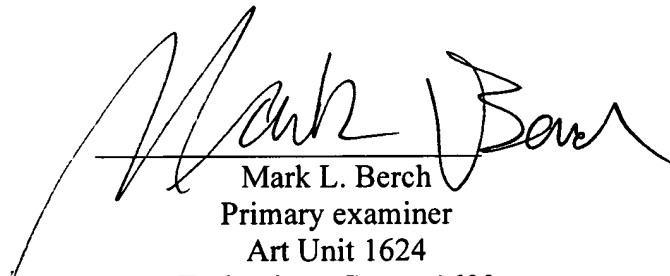
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susanna Moore whose telephone number is (571) 272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SM



Mark L. Berch
Primary examiner
Art Unit 1624
Technology Center 1600